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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/525,449

11/09/2005

Isabelle Poquet

1169-034

3827

20529 7590 03/24/2010
THE NATH LAW GROUP
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EXAMINER

MARVICH, MARIA

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

03/24/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|--|--|--|--|
| <p align="center">Advisory Action Before the Filing of an Appeal Brief</p> | <p>Application No. 10/525,449</p> | <p>Applicant(s) POQUET ET AL.</p> | |
| | <p>Examiner MARIA B. MARVICH</p> | <p>Art Unit 1633</p> | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 March 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: _____.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

/Maria B Marvich/
Primary Examiner, Art Unit 1633

Continuation of 3. NOTE: Applicants have added new claim 36 which is directed to an expression cassette comprising a bacterial promoter pZN (SEQ ID NO:1) and a restriction site to place a sequence under transcriptional control of the promoter wherein the cassette does not comprise any part of ZitS. Previously, the claims were drawn to an expression cassette comprising the pZn promoter operably linked to ZitR wherein the sequence did not comprise any part of ZitS. Given that the term expression cassette does not necessarily encompass the entirety of a vector, it is not clear that the art of record, Poquet, I., Ehrlich, S.D. and Gruss, A. An export-specific reporter designed for gram-positive bacteria: application to *Lactococcus lactis*, does not read on this claim. Specifically, the sequence of Poquet et al comprise the promoter sequence operably linked to a number of restriction sites, i.e. BsrI at nucleotide 796 absent any other sequences can be considered an expression cassette. Such new consideration means that the reference reads on claim 36. As well, it is unclear if rejoinder is requested. If so, consideration of the rejoined claims constitutes a requirement for new consideration.

Continuation of 11. does NOT place the application in condition for allowance because: Applicants' arguments regarding the rejection under 35 USC 112, first paragraph to require a biological deposit have been considered but are not persuasive. Applicants have simply argued that the sequence was present at the time of filing. However as the sequence has been recited, it is essential subject matter and as essential subject matter must be presented. To overcome the rejection, applicants must submit the sequence of AAK06214 in a compliant sequence listing and provide evidence that the sequence submitted is the sequence available at the time of filing. The listing must be accompanied by CRF, a letter stating that the listing and CRF are the same and the submission does not constitute new matter and a letter directing its entry into the specification.

Continuation of 13. Other: Claim 17 should be amended to recite --said extracellular targeting sequence comprises the sequence of-- as the provided sequence appears to be the signal peptide and not the gene comprising the signal sequence. As well, claim 18 should be reformatted to recite, --a nucleotide sequence under the transcriptional control of the pzn promoter fused to a reporter gene-- for clarity.